UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,995	10/28/2005	David John Grainger	50653/003001	8214

21559 7590 06/24/2010

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

NOTIFICATION DATE	DELIVERY MODE
06/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/547,995	GRAINGER, DAVID JOHN	
	Examiner	Art Unit	
	TERESA WESSENDORF	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16-41 and 43-49* is/are pending in the application.

4a) Of the above claim(s) *1-12,22-40,45-47 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,16-21,41,43,44 and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/22/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claims 17 and 47 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: n being defined as 9-12 as recited in claim 17 is distinct from the originally filed and examined n=8.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 17 and 47 are withdrawn from consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

Applicant notes that amendment of claim 17 to specify that n = 8-12 (rather than 8) and the addition of claim 47 to specify that n = 8, 9, 10, or 12 was not considered by them to be in a separate group upon submission of the amendment, as these claims are within the scope of the examined claims. This notwithstanding, Applicant reserves the right to have claims 17 and 47 rejoined if they are to remain withdrawn at this time, in view of linking claim 13, and also reserves the right to petition this requirement. Applicant respectfully requests

reconsideration and withdrawal of the requirement, so that claims 17 and 47 can be examined at this time.

In view of applicants' arguments claims 17 and 47 would be examined to the extent that each reads on the elected species only i.e., n=8. The other species wherein n= 9-12 are withdrawn from further consideration as being drawn to the non-elected species.

[Please see the Office action mailed on 1/21/09 at e.g., page 11 wherein the species of n=9-12 were not examined.]

Status of the Claims

Claims 1-13, 16-41 and 43-49 are pending.

Claims 1-12, 22-40, 45-46, 47 and 49 (non-elected species) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected and non-examined inventions/species.

Claims 14-15 and 42 have been cancelled.

Claims 13, 16-21, 41, 43-44 and 47-49(only for the elected species) are under examination. (Please note the withdrawal of claims 17 and 47 from examination as being drawn to non-examined species as stated above).

Information Disclosure Statement

In view of the newly submitted PTO-1449 filed on 2/22/10, the IDS will be considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13, 16-21, 41, 43-44 and 47-49 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

Claim 13 and dependent claims are drawn to a library comprising a plurality of mixtures of peptides having the formula of X1a….Xn.

The claimed library is not supported by a specific asserted utility. Attention is drawn to applicant's REMARKS filed on 2/22/10 at e.g., page 16, 2nd complete paragraph. Applicant states that the libraries of the invention are **general**, and that

there does not need to be a particular purpose/function. Those of skill in the art have been using libraries routinely for many years, and would understand how to apply the presently claimed libraries in screening methods. The specification at e.g., page 22 recites the use of said library in screening methods. 35 U.S.C. 101 requires that an invention must be useful. The reviewing courts have applied the labels "specific utility" (or "practical utility") to refer to this aspect of the "useful invention" requirement of this statute. Nelson v. Bowler, 626 F.2d 853,206 USPQ 881, 883 (CCPA 1980). A library that is general and does not need to be of a particular purpose/function does not comply with 35 USC 101 requirements that in order to obtain a patent the product must be useful. The USPTO Utility Guidelines, page 12 states that inventions that have a specifically identified utility must be distinguished from those whose utility requires further research i.e., screening to identify or reasonably confirm. It is not the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained

an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates. See In re Kirk, 153 USPQ 48, 53 (CCPA 1967). Attention is further drawn to MPEP 2117 as to the numerous examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities. Examples are a claim to an intermediate product (such as the instant library) for use in making a final product that has no specific, substantial and credible utility or a method of assaying for or identifying a material that itself has no specific and/or substantial utility.

This is not to say that inventions that are to be used exclusively in a research setting (i.e., research tools) always lack a specific asserted utility, indeed, many research tools such as telescopes, gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility. Research tools (such as gas chromatographs, screening assays, etc.) are useful in the sense that they can be used in conjunction with other method steps to evaluate materials other than themselves or to arrive at some result. The claimed libraries are not research tools in this

sense. Rather, they are themselves the subject of basic research, whose usefulness or lack thereof has yet to be established. There is no evidence of record or any line of reasoning that would support a conclusion that the claim library, as of the filing date will be useful (see applicant's REMARKS as to the library being general). Until some actual and specific significance can be attributed to the library, an artisan would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent, specific, and substantial or "real world" utility as of the filing date.

Claims 13, 16-21, 41, 43-44 and 47-49 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The specification fails to teach how to use the claim library as set forth under the 35 USC 101 rejections above.

Furthermore, the specification fails to teach how to make and use the claimed broad mixtures of peptides or library of

mixtures wherein each of the amino acids in the mixtures comprised any of number of groups of amino acids. The claimed number of groups would encompass a huge combination of different amino acids in a group hence, a potentially huge numbers of mixtures of peptides. The specification recites the specific groups of e.g., hydrophobic amino acids. However, the claimed groupings do not fall within the disclosed groups. Because peptide sequence hence, its conformation dictates the function of the peptide, it is not clearly apparent from the huge scope of the claims the ones that would result in a peptide having a function. Neither does it disclose a library that can be screened for a particular purpose/function. The high unpredictability in the peptide art is notoriously known in the art. The art is inherently unpredictable because it is not possible to predict which predetermined (variations) of amino acids would result in the desired mutant with a desired binding function. It is generally known that the conformational freedom that promotes binding, e.g., by modifying the peptides, might be restricted which may likely perturb the function and stability of the peptide (protein) in ways difficult to predict and measure. Some peptides accommodate variations at numerous sites throughout their primary sequence. Others are much less accommodating. It is difficult in general to predict which

peptides are robust to variations, and which sites in a particular peptide are best suited to variations of multiple independent sequences. The complex spatial configuration of amino acid side chains in peptides and the interrelationship of different side chains in the randomized sites are insufficiently understood to allow for such predictions. Each of the 19 amino acids is integrated at different frequencies due to the degeneration of the genetic code. For instance, serine is integrated six times more often than tryptophan, and three times more often than aspartic acid. It would therefore require an enormous effort to isolate mutants corresponding to amino acids represented only once or twice. Because the art is unpredictable, applicants' specification reasonably would not have assured persons skilled in the art that the numerous undefined molecule in a peptide mixture that would result in a mutations having function without undue experimentation. Applicants do not adequately enable persons skilled in the art to readily determine such. Applicants need not guarantee the success of the full scope of the claimed invention. However, skilled artisans are provided with little assurance of success.

Response to Arguments

Applicant submits that because the size of the mixtures/libraries is "huge," there is an increased chance of identifying relevant peptides in the mixtures/libraries. Further, even if a mixture/library of the invention was to be screened in a particular experiment and no relevant hits identified, that does not mean that the mixture/library is not useful. Rather, it is standard in the art to have to use multiple libraries to find a desired target molecule, and it cannot be that the claimed libraries would be found to never include such a target. Applicant further submits that it is unclear what the difficulty could be in selecting groups of amino acids that meet the criteria of the claims and using them to make peptides of the claimed groups and libraries. Those of skill in the art can take, for example, the 20 naturally occurring amino acids made divide them up according to the parameters of the claims. If the chemistry of a particular sequence is such that it is not amenable to generation of a peptide that may be a useful target in a particular assay, then there would be other sequences that are, given the large numbers of possible sequences.

In reply, the court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), held that a patent is not a hunting license (i.e., to

identify relevant(irrelevant) peptides in a mixtures). It is not a reward for the search, but compensation for its successful conclusion. [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. Thus, it is more likely than not that a relevant peptide would not be identified by the huge scope of the claimed library. One can make a huge library but the challenge still faced by skilled artisan is screening this huge collection to identify a compound that is useful and of benefit to the public.

Applicant submits that it is a fundamental feature of a library to include many peptides, with many not being relevant to a particular screen. Further, Applicant submits that the libraries of the invention are general, and that there does not need to be a particular purpose/function. Those of skill in the art have been using libraries routinely for many years, and would understand how to apply the presently claimed libraries in screening methods.

In reply, if the library contains numerous peptides, then the peptide library is not a specific compound. Rather as

applicant sates above a general one what does not need a particular purpose/function. However, the law requires the compound to be of specific utility, not a general one. Please see the 35 USC 101 rejections above. Furthermore, if the library does not have a particular purpose/function hence, it is not seen how it can be of use to the public and deserving of a patent.

Applicant notes that the invention does not focus on making variations of known sequences but, rather, concerns sequences (many of which may be new) that are made using the specified groups of amino acids. Although certain sequences obtained in this manner may possibly result in a peptide that, for example, does not include an epitope recognized by an antibody that is being screened against the library, there are so many different sequences in the mixtures/libraries, which provides the opportunity for such sequences to exist.

In reply, the claim selecting independently the amino acid from groups of amino acids would read on a method of making variations. Please see further applicant's arguments below.

The claims do not recite for epitopes recognized by antibody rather only peptides of the given formula, with no purpose or function, as stated above.

Applicant submits that they are not claiming methods for the identification of a particular type of compound, and that it is standard in the art, in general, to make and use peptide libraries. The mixtures/libraries of the present claims represent a unique, novel, and non-obvious subset of peptide mixtures/libraries, in which the level of variability permitted at each amino acid position, is limited in a very particular way. As discussed above, the manner by which this variability is obtained is delineated in the claims.

In reply, the variability delineated in the claims involves selecting independently from set groups of amino acids, which albeit not positively recited in the claims are method claims. Applicant has not proffered any evidence to support their arguments that the instant library of no defined structure and involves selection steps are adequately enabled.

Written Description Rejection

B). The specification fails to provide a description for the claim library having the variable claim structure X1-----Xn. The specification merely provides in general terms the claim library of said X1…Xn structure but the exemplification is nil. The Examples at e.g., pages 38-43, which normally provides the details of the invention, however describes antigen/antibody library which does not correspond to the claims structure of X1…Xn. Thus, it is not apparent from the Examples if the antigen/antibody library are the (same) compounds of the structure as now claim.

The written description requirement clearly requires that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, 2nd paragraph

Claims 13, 16-21, 41, 43-44, as amended and new claims 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, only for the **maintained rejections** as set forth below.

7. Claims 41, 43-44 and 49 are indefinite as to the components of a kit such that the kit can be used for the intended purpose e.g., instructions as to the use of the kit.

Response to Arguments

Applicant submits that instructions for use are not necessarily required for a kit. For example, there may be a package including multiple kits and there may be one set of instructions in the package that is to be used with respect to each of the individual kits. The kits in such a package may include only the materials to be used, and not the instructions. In view of such an example, Applicant respectfully requests that this rejection be withdrawn. If the rejection is maintained, Applicant requests citation of an authority upon which this

rejection is based, so that it can be considered in relation to these claims.

In reply, how can one use a kit without any instructions? The example cited by applicant above clearly uses an instruction albeit use for the multiple kits. This provides the authority applicant is asking for. See also the prior art teachings, the Lynch reference, below.

A). Claim 18 and new claim 49 are indefinite in the recitation of the "library comprises mixtures representing all possible combinations of the groups", when e.g., there are only two groups.

Response to Arguments

Applicant states that this rejection has been met by the present amendments of claims 18 and 49, by which the above-quoted statement as it appears in claims 18 and 49 is amended as follows "library comprises mixtures representing all possible combinations of the groups that are present in the mixtures".

In reply, the amendments to the claims have not been overcome as the concept is the same.

B). Amended claim 41 is unclear as to the type or kind of "different" tag that can be attached to the different mixtures, especially in the absence of positive support in the specification as to what is included or precluded by said different tag.

Response to Arguments

Applicant notes that "different" tags are tags that can be differentiated from one another by some manner. Examples are provided in the application, such as the aluminum bar-coded particles described on page 28, lines 3-29.

In reply, applicants do not seem to appreciate the above rejection. It Is not the definition at issue as the definition of the "different" tags are clear. The issue is the metes and bounds of the claimed "different tags" which are infinite i.e., of no set boundaries. Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim

limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment. Superguide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). MPEP 2111.01(II).

C). Claim 13 is indefinite as to the four groups of amino acids being "independently" selected from 5 amino acids.

What is the basis by which one will select "independently" one amino acid over the other in groups of e.g., four (4) out of five amino acids?

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102/103

I. Claims 13 and 16-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Houghten et al (Nature, 1991). [Since the claims are subject to several interpretations hence, the applicability of the 102/103 is proper.] See MPEP 2116.01.

Houghten et al discloses, throughout the article, at e.g., page 84 a mixtures of peptides and the heterogeneous libraries formed from the mixtures. The mixtures of peptide or library of hexapeptides comprises the formula as shown at Table 1, page 84, col. 2. See also, Fig. 1 at page 85 and Table 2 at page 86. Therefore, the specific mixture of Houghten which describes specific residues anticipates or renders obvious the broad claimed mixtures/libraries with no defined structures or sequences.

Please note that the responses below have been modified to address applicant's arguments and/or amendments to the claims.

Response to Arguments

Applicant states that in Table 1, as cited by the Examiner, the peptide mixtures of a-d each include "X," which is not defined. Therefore, it is impossible to determine whether the mixtures of a-d comprise amino acids as specified in the present claims, which are selected from four groups of five amino acids, or two groups of ten amino acids, wherein no amino acid is present in more than one group (and for each peptide in the

mixture the amino acid at the same position of X1-Xn is selected from the same group). Rather, it is more likely that the X's of Houghten covers all amino acids.

As to the peptides of e, if these represent a group of peptides, they do not meet the limitations of the present claims, as position 6 of the peptides of e include more than 10 different amino acids. In another example cited by the Examiner, Figure 1 describes several peptides, each including multiple X residues, which are defined as representing an equimolar mixture of 18 different amino acids. These peptides are not within a mixture of the present claims, which require that each X represent an amino acid selected from four groups of five amino acids or two groups of ten amino acids.

In reply, Houghten at e.g., page 85 defines X as 18 of the natural amino acids and substitutes to the X thus giving specific peptide sequences which would meet the broad claimed library of peptide of no definite sequence, Xn. The claim limitation of "independently selected" is a process step rather than a compound limitation as claimed. The compound is described in terms of its structure or formula and not by which it is selected from a given amino acids be it singly or in multiples as in groups of four(4). See the Methods of Fig. 1 at e.g., page

85 and the species at Table 3, page 86. Thus, the claimed library of no definite length or sequence that would only be selected from a given groups of undefined amino acids are fully met by the hexapeptide of Houghten. The process steps of selecting from groups of amino acids of a given set would have been obvious to do given the hexapeptide of Houghten and selection from the given 18 residues independently selected therewith. It would have been obvious to one having ordinary skill in the art at the time the invention was made to group the 20 naturally occurring amino acid residues into sets e.g., 4 out of 5 amino acids given the few naturally occurring amino acids.

As held by the majority in **Merck & Co. Inc. v. Biocraft** Laboratories, Inc., 874 F.2d 804, 10 USPQ 2d 1843 (Fed. Cir. 1989), at 10 USPQ 2d 1846:

> That the '813 patent discloses a multitude of effective combinations does not render any particular formulation less obvious. This is especially true because the claimed composition is used for the identical purpose taught by the prior art. See In re Corkill, 771 F.2d 1496, 1500, 226 USPQ 1005, 1008 (Fed. Cir. 1985) (obviousness rejection of claims affirmed in light of prior art teaching that "hydrated zeolites will work" in detergent formulations, even though "the inventors selected the zeolites of the claims from among "thousands of compounds"); In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971) (obviousness rejection affirmed where the disclosure of the prior art

> was "huge, but it undeniably include[d] at least some of the compounds recited in appellants generic claims and it is of a class of chemicals to be used for the same purpose as appellant's additives").

Herein only few amino acids i.e., 18 can be grouped into e.g., 4 groups out of the 18 amino acids (instead of 5 and still expect to obtain from the 20 natural amino acids that can be independently selected from therewith, a general library as claimed and argued above.

II. Claims 13, 16-21, 41, 43-44 and 47-49 are rejected under 35 U.S.C. 102(e) as anticipated by or in the alternative under 35 USC 103(a) being obvious over Fowlkes et al (USP 6617114). [Since the claims are subject to several interpretations hence, the applicability of the 102/103 is proper.] See MPEP 2116.01.

Fowlkes et al disclose throughout the patent, at e.g., col.16, line 46 up to col. 18, line 16:

> A peptide library …. at least some of whose members are peptides having three or more amino acids connected via peptide bonds. In an oligopeptide library, the lengths of

the peptides do not exceed 50 amino acids….. A biased peptide library is one in which one or more (but not all) residues of the peptides are constant residues. The individual members are referred to as peptide ligands (PL). In one embodiment, an internal residue is constant, so that the peptide sequence may be written as (Xaa)m-AA1-(Xaa)n… Where Xaa is either any naturally occurring amino acid, or any amino acid except cysteine, m and n are chosen independently from the range of **2 to 20**, the Xaa may be the same or different, and AA1 is the same naturally occurring amino acid for all peptides in the library but may be any amino acid. Preferably, m and n are chosen independently from the range of 4 to 9. …[M]ore preferably, that m and n are not different by more than 2…. The most preferred libraries are those in which AA1 is tryptophan, proline or tyrosine. Second most preferred are those in which AA1 is phenylalanine, histidine, arginine, aspartate, leucine or isoleucine. Third most preferred are those in which AA is asparagine, serine, alanine or methionine. The least preferred choices are cysteine and glycine. These preferences are based on evaluation of the results of screening random peptide libraries for binding to many different TPs.
See further all the Examples which describe the specifics of the library containing tag. (Emphasis added.)

Claims 41 and 43-44 drawn to a kit is disclosed at col. 31, line 15.

Fowlkes which describes specific residues for the library fully meet or render obvious the broad claimed mixtures/libraries containing any amino acid sequence.

Response to Arguments

Applicant states that Fowlkes does not anticipate the present claims. In particular, the claims require that each X in

the peptides of the mixture be from four groups of five amino acids, or two groups of ten amino acids, wherein no amino acid is present in more than one group (and for each peptide in the mixture the amino acid at the same position of Xl-Xn is selected from the same group). Based on this, each position can have only one of five possible amino acids or one of ten possible amino acids, and cannot have any one of twenty possible amino acids. The peptides of Fowlkes, in contrast, can include positions that have any amino acid (and not just one of five or one often possible amino acids).

In reply, attention is drawn to the teachings of Fowlkes above which discloses Xaa as either any naturally occurring amino acid, or any amino acid except cysteine, m and n are chosen independently from the range of **2 to 20**, the Xaa may be the same or different, and AA1 is the same naturally occurring amino acid for all peptides in the library but may be any amino acid. Preferably, m and n are chosen independently from the range of 4 to 9, which includes the elected claim 8.

Please see further Houghten above as to the groupings or selection of 4 for 5 amino acids or 2 for ten groupings.

III. Claims 13, 16-21, 41, 43-44 and 47-49 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lynch et al (5962244). [Since the claims are subject to several interpretations hence, the applicability of the 102/103 is proper.] See MPEP 2116.01.

Lynch discloses throughout the patent at e.g., col. 13, line 13 up to col. 14, line 67:

A combinatorial chemical library…..such as a polypeptide ….formed by combining a set of chemical building blocks (amino acids) in every possible way for a given compound length (i.e., the number of amino acids in a polypeptide compound).

Lynch discloses compositions and kits……for…screening assays …. The kits can include any of the compositions noted above, and optionally further include additional components such as instructions to practice a high-throughput method of screening for a peptidyl transferase activity modulator…. robotic armature for mixing kit components, and the like.

Lynch describes specific residues for the library that fully meet or render obvious the broad claimed mixtures/libraries containing any amino acid sequence (i.e., of undefined amino acid peptide and recites only for the selection process).

IV. Claims 13-21 and 47-48 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lam et al (5858670) for reasons of record as reiterated below.

Lam discloses throughout the patent at e.g., col. 3, line 14 up to col. 7, line 10:

….[A] **library** of bio-oligomers comprising all possible combinations of subunits…..FIG. 1. Scheme for random peptide synthesis using the split synthesis method for a random tripeptide with a terminal tryptophan added: X-X-X-W (wherein X=S, A, or V...).

Lam which describes specific residues for the library fully meet or render obvious the broad claimed mixtures/libraries containing any amino acid sequence. (i.e., of undefined amino acid peptide and recites only for the selection process).

Response to Arguments

Applicant submits that, as discussed above, the present claims do not cover libraries that contain "any amino acid sequences" as disclosed by Lynch and Lam et al.

Rather, the variability of the sequences of the libraries is limited, as is clearly delineated in the claims.

In reply, the reasons above are incorporated herein since applicant merely incorporates his responses from the above.

It is noteworthy to cite Lam, for example, at e.g., col. 9, line 5 -line 60:

> If the hexapeptide is to be comprised of five different amino acids, the method could be employed using five aliquots, each containing a different amino acid, at each coupling step. If, however, the hexapeptide is to be comprised of any of the basic set of twenty amino acids, the method could be employed using twenty aliquots at each coupling step.
>
> …The synthesis of pre-determined sequences involves the use of specific...appropriately protected amino acids during specific coupling steps. For example, **one may select** amino acids at specific coupling steps such that the resulting peptides will have a probability or preference for a particular secondary structure, e.g. .beta.-sheet, .alpha.-helix, .beta.-turn, etc. For example, .alpha.-helix would be preferred **if Glu, Ala, Leu, His, Trp** are used as preferred amino acids; on the other hand .beta.-sheets would be preferred if Val, Ile, Tyr and Met are used. Alternatively, if **Gly, Asn, Ser, Pro, Asp** are used, a .beta.-turn structure would be preferred.

Thus, Lam teaches or at least suggests, the 5 amino acids from which four groups could obviously be selected.

As read in light of the specification at e.g., paragraph [0130] which states:

> In such a mixture of peptides it is possible to specify that no amino acid is present in more than one of the groups of amino acids, i.e. that each amino acid will only appear when it's group is selected at a particular position. It is further possible to specify that each group of amino acids contains the same number of different amino acids. Thus for the twenty amino acids listed above, **one could envisage** dividing them into two groups of ten amino acids, four groups of five or five groups of four. (Emphasis added.)

V. Claims 13, 16-21, 41, 43-44 and 47-49 rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The specification at e.g., page 41, lines 20-25 recites "..**we** performed the actual DMI procedure….-we aim to add between 10 and 200 times as many individual tags are there are discrete components to the library…"

Thus, applicant appears not to be the sole inventor of the claim subject matter since the specification which recites "we" indicate other inventors of the claimed subject matter.

No claim is allowed.

Conclusion

Crea (USP 20030228302) discloses universal libraries for immunoglobulin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA WESSENDORF whose telephone number is (571)272-0812. The examiner can normally be reached on flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. D. Wessendorf/

Primary Examiner, Art Unit 1639